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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,213	10/31/2003	Martin T. Gerber	P-11667.00US	1507

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EXAMINER	
SMITH, RUTH S	
ART UNIT	**PAPER NUMBER**
3737	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/698,213	GERBER ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Objections

Claim 15 is objected to because of the following informalities: In claim 15, "the second actuator" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3,5-7,9-18,20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Epstein et al (2003/0028172). Desai discloses a method and apparatus for delivering a therapeutic agent and surgical tool to the diseased or injured site by imaging the target location such as prostate gland with ultrasound imaging device as shown in figure 3. The surgical tool or device can either be introduced noninvasively via body cavity or invasively via insertion needle where the needle insertion is through the perineum where the treatment fluid, i.e. therapeutic agent such as denervating agent is introduced to the patient. The ultrasound imaging probe 36 provides feedback to verify the location of the needle placed in the patient to

deliver the therapeutic agent to desired location. Desai further discloses the secondary reservoir inasmuch as figure 2 shows that the syringe 34 in interchangeable to provide multiple therapeutic agent injection from multiple syringes. Desai fails to disclose the use of a spring-loaded needle. The use of spring-loaded needles are in the art are old and well known as seen for example in Epstein et al. It would have been obvious to one skilled in the art to have modified Desai such that the needle used is a spring-loaded needle. Such a modification merely involves the substitution of one known type of needle for another. The advantage of a spring-loaded needle in the apparatus of Desai would be that it would allow for more efficient and effective actuation of the needle into tissue as taught by Epstein et al.

Claims 4, 8, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Epstein et al as applied to claim 1, 7, and 11 above, and further in view of Henley et al (US 6,477,410 B1). Desai is silent as to the use of botulinum toxin. This particular application of botulinum toxin to the prostate gland is well known in the art as seen in Henley et al where the botulinum toxin is applied to prostate gland for therapy. Therefore, it would have been obvious to one of ordinary skill in the art to have applied the teachings of Henley et al's botulinum toxin injection to prostate gland to the method and apparatus of Desai's image feedback guidance to accurately deliver the botulinum toxin to the prostate gland.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Epstein et al (2003/0028172) and Luther et al (7,037,294). Desai discloses a method and apparatus for delivering a therapeutic agent and surgical tool to the diseased or injured site by imaging the target location such as prostate gland with ultrasound imaging device as shown in figure 3. The surgical tool or device can either be introduced noninvasively via body cavity or invasively via insertion needle where the needle insertion is through the perineum where the treatment fluid, i.e. therapeutic agent such as denervating agent is introduced to the patient. The ultrasound imaging probe 36 provides feedback to verify the location of the needle placed in the patient to

deliver the therapeutic agent to desired location. Desai further discloses the secondary reservoir inasmuch as figure 2 shows that the syringe 34 in interchangeable to provide multiple therapeutic agent injection from multiple syringes. Desai fails to disclose the use of a spring-loaded needle or a wheel used to rotate the orientation of the needle. The use of spring-loaded needles are in the art are old and well known as seen for example in Epstein et al. It would have been obvious to one skilled in the art to have modified Desai such that the needle used is a spring-loaded needle. Such a modification merely involves the substitution of one known type of needle for another. The advantage of a spring-loaded needle in the apparatus of Desai would be that it would allow for more efficient and effective actuation of the needle into tissue as taught by Epstein et al. Luther et al disclose a needle having a wheel which permits rotation of the needle to a desired orientation. It would have been obvious to one skilled in the art to have further modified Desai such that the spring-loaded needle includes a wheel to rotate the needle to a desired orientation. Such a modification allows to needle to be located more precisely in the target tissue as desired.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3-12,15-24 of copending Application No. 10/698,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because with respect to claims 1-21 of the present application, the claims involve an obvious broadening of the claims in application serial no. 10/698,676. With respect to claims 22-24 of the present application, the specific type of mechanism used to position the needle at the correct orientation would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS